

Claim Amendments

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1. (Previously Amended) A hemofiltration system comprising:  
a hemofiltration machine having at least one flow control and a removable extracorporeal circuit, mounted in a removable cartridge, for circulating blood from an individual through a hemofilter to remove waste and to return blood and replacement fluid to the individual after removal of waste, the extracorporeal circuit including a waste discharge path to convey waste fluid to a waste receiving unit and a replacement fluid path for infusing replacement fluid into said individual, said replacement fluid path including a sterilizing filter positioned to prevent contaminants from being infused into said individual.

B5 2. (Previously Amended) A system according to claim 1 wherein said sterilizing filter is an inline filter filtering all replacement fluid infused into said individual.

3. (Previously Amended) A system according to claim 2 wherein sterilizing filter is integrally connected to the replacement fluid path.

4. (Previously Amended) A system according to claim 2 wherein said replacement fluid path includes a connector upstream of said sterilizing filter for connecting to a replacement fluid reservoir.

5. (Previously Amended) A system according to claim 1 wherein said sterilizing filter includes a 0.2 micron filter medium.

6. (Currently Amended) A hemofiltration system comprising an extracorporeal circuit for circulating blood from an individual through a hemofilter to remove waste from a

filtrate side of said hemofilter and, to return blood and replacement fluid to the individual after removal of waste, waste fluid being the only fluid contacting the waste side of said hemofilter with no fluid entering said waste side; the extracorporeal circuit including a replacement fluid path to convey replacement fluid from a source to the extracorporeal circuit, the replacement fluid path including a sterilizing filter to avoid contamination of the extracorporeal circuit, wherein said source contains no waste fluid.

7. (Original) A system according to claim 6 wherein the source comprises at least one container holding replacement fluid.

B5 8. (Original) A system according to claim 6 wherein the sterilizing filter is integrally connected to the replacement fluid path.

9. (Currently Amended) A system according to claim 6 wherein the replacement fluid path terminates in multiple fluid branches, each fluid branch ~~including a connector to couple a~~ being connectable to a respective source container of replacement fluid to the replacement fluid path.

10. (Original) A system according to claim 6 wherein the replacement fluid path includes a separate replacement fluid set comprising multiple branches, each branch including a connector to couple a source container of replacement fluid to the set, and wherein the replacement fluid path includes a set connector to releasably join the replacement fluid set to the replacement fluid path.

11. (Original) A system according to claim 10 wherein the sterilizing filter is in the separate replacement set.

12. (Original) A system according to claim 10 wherein the sterilizing filter is in the replacement fluid path upstream of the set connector.

13. (Currently Amended) A hemofiltration system comprising a hemofiltration machine including a chassis and at least one flow controlling element on the chassis, an extracorporeal circuit for circulating blood from an individual through a hemofilter to remove waste and to return blood to the individual after removal of waste, a portion of the extracorporeal circuit being integrated, at least in part, within a fluid processing cartridge orienting the extracorporeal circuit for mounting as an integrated unit on the chassis with portions of the extracorporeal circuit in operating engagement with the flow controlling element and for removal as an integrated unit from the chassis, and a controller for the hemofiltration machine operable in a hemofiltration mode to operate the flow controlling element, when the fluid processing cartridge is mounted on the chassis, to convey an individual's blood through the extracorporeal fluid circuit to a hemofilter to remove waste fluid and to supply replacement fluid from a source of replacement fluid that is isolated from a flow of waste, ~~the controller also operable in a dwell mode to suspend the hemofiltration mode and retain the fluid processing cartridge on the chassis between multiple intermittent hemofiltration sessions during a prescribed time period~~, the fluid processing cartridge including a sterilizing filter arranged to filter replacement fluid prior to infusion.

14. ~~(Canceled)~~

15. (Currently Amended) A system according to claim 13 wherein the extracorporeal circuit includes a replacement fluid path to convey replacement fluid from [a] said source of replacement fluid to the extracorporeal circuit, said sterilizing filter being incorporated in said replacement fluid path to avoid contamination of the extracorporeal circuit.

16-19. ~~(Canceled)~~

20. (Original) A system according to claim 13 wherein, during the hemofiltration mode, the controller operates the flow controlling element to convey blood through the hemofilter at a blood flow rate of at least 300 ml/min.

21-28. ~~(Canceled)~~

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29. (Currently Amended) A method for carrying out hemofiltration comprising the steps of (i) operating a hemofiltration machine to convey an individual's blood through an extracorporeal fluid circuit to a hemofilter to remove waste fluid and dispose of said waste fluid, (ii) introducing replacement fluid through a replacement fluid path connecting a source of replacement fluid to said individual, said replacement fluid path forming [that forms] a part of the extracorporeal circuit and said source of replacement fluid being isolated from said waste fluid and said waste fluid being the only fluid contacting a filtrate side of said filter, (iii) preventing contamination of the extracorporeal circuit by locating a sterilizing filter in the replacement fluid path.

30. (Original) A method according to claim 29 wherein steps (i), (ii), and (iii) are conducted during multiple intermittent sessions during a prescribed time period.

31. (Original) A method according to claim 30 further including the step of introducing a bacteriostatic agent into the extracorporeal circuit between the multiple intermittent sessions.

32. (Currently Amended) ~~A method according to claim 30, further including the step of~~ A method for carrying out hemofiltration comprising the steps of (i) operating a hemofiltration machine to convey an individual's blood through an extracorporeal fluid circuit to a hemofilter to remove waste fluid and dispose of said waste fluid, (ii) introducing replacement fluid through a replacement fluid path connecting a source of replacement fluid to said individual, said replacement fluid path forming [that forms] a part of the extracorporeal circuit and said source of replacement fluid being isolated from said waste fluid and said waste fluid being the only fluid contacting a filtrate side of said filter, (iii) preventing contamination of the extracorporeal circuit by locating a sterilizing filter in the replacement fluid path;

wherein steps (i), (ii), and (iii) are conducted during multiple intermittent sessions during a prescribed time period; subjecting the extracorporeal circuit to refrigeration between the multiple intermittent sessions.

33. (Original) A method according to claim 30 wherein the prescribed time period is between about 48 hours and about 120 hours.

34. (Original) A method according to claim 30 wherein the prescribed time period is between about 72 hours and about 80 hours.

B5 35. (Original) A method according to claim 29 further including the step of (iv) performing steps (i) to (iii) at least four times weekly.

36. (Original) A method according to claim 29 wherein, in step (i), blood is conveyed through the hemofilter at a blood flow rate of at least 300 ml/min.

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37. (New) A hemofiltration system comprising:  
an extracorporeal fluid circuit having a blood circuit connectable to a patient and a filter such that blood may be circulated through said blood circuit;  
B6 said extracorporeal fluid circuit including a waste circuit connectable to said filter to convey waste fluid away from said filter and a replacement fluid circuit connectable between a source of replacement fluid and a patient;

a balancing mechanism configured to provide replacement fluid through said replacement fluid circuit at a first rate substantially equal to a second rate of removal of waste through said waste circuit;

said waste and replacement fluid circuits being isolated from each other such that no flow can exist between said waste circuit and said replacement fluid circuit;

said replacement fluid circuit including an inline sterilizing filter.

38. (New) A system as in claim 37, wherein said source of replacement fluid includes a source of sterile fluid contained in a replacement fluid container.

39. (New) A system as in claim 37, wherein said sterilizing filter includes a membrane effective to eliminate pyrogenic material.

40 41. (New) A hemofiltration system comprising:

an extracorporeal fluid circuit having a blood circuit connectable to a patient and a filter such that blood may be circulated through said blood circuit;

said extracorporeal fluid circuit including a filtrate circuit connectable to said filter to convey filtrate fluid away from said filter and a replacement fluid circuit connectable between a source of replacement fluid and a patient;

a balancing mechanism configured to provide replacement fluid from a source container of replacement fluid through said replacement fluid circuit;

said replacement fluid circuit including an inline sterilizing filter.

41 42. (New) A system as in claim <sup>40</sup>41, wherein said replacement fluid circuit is configured to convey replacement fluid from said source container, through said balancing mechanism, to said blood circuit and said extracorporeal fluid circuit is otherwise configured such that said replacement fluid circuit is a sole source of fluid to said patient other than blood conveyed in said blood circuit.

42 43. (New) A hemofiltration system, comprising:

an arterial line configured to convey blood from a patient to a filter;

a venous line configured to convey blood from said filter back to said patient;

a filtrate line configured to convey blood filtrate away from said filter;

a replacement fluid line configured to convey replacement fluid from a replacement fluid source to said venous line;

said replacement fluid line having a filter effective to remove pyrogens;

B6 said replacement fluid line providing fluid flow communication only between said replacement fluid source and said venous line without receiving fluid from another source.

~~43~~ ~~44~~. (New) A system as in claim <sup>42</sup>~~43~~, wherein said replacement fluid line has at least one bag spike.

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